

PharmAust Completes Successful Taste Mask Testing of New Tablet

- Previous unpalatable monepantel taste was a major barrier that now appears overcome as beagles readily accept tablets voluntarily
- PharmAust settles on taste test data to commence Phase I trials in dogs
- Success in dogs is expected to translate to success in less taste-sensitive humans

11 February 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, has successfully completed its monepantel taste masking program in healthy beagle dogs. This work was conducted in collaboration with BRI Biopharmaceutical Research Inc., Vancouver, Canada and Catalent Pharma Solutions in San Diego, USA.

Previously, PharmAust had difficulty with administration of monepantel to human and dog cancer patients in clinical trials due to a bad taste associated with the original formulation. Despite apparent early success in the clinical trials, the very poor taste of the drug meant that trial completion was put on hold.

BRI and Catalent were subsequently charged with establishing a new drug product and providing a scaled GMP-grade product for clinical trials. As announced on 15 October 2018, BRI established a suitable micronized tablet prototype that enabled superior blood levels of drug, more than sufficient for clinical trial work. As announced on 13 November 2018, Catalent commenced procedures to scale production of this tablet for clinical trials. Prior to commencing scaled tablet manufacture, however, the taste of the new micronized tablet had to be formally tested.

To determine a willingness to take the new monepantel tablets voluntarily, beagles were given prototype tablets made by Catalent that were either uncoated or coated with a United States Federal Drug Administration (US FDA) approved neutral tasting agent. Beagles readily took both coated and uncoated tablets, voluntarily, either directly from administrators' hands or from the floor. PharmAust was therefore provided a choice of progressing either of the tablet candidates through subsequent clinical trials. PharmAust has chosen uncoated tablets in a first step.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "These test outcomes are very pleasing. The major aims of reformulation were to find a drug product that could provide a high dose and neutralise the poor taste of the original formulation. Both of these aims have now been met and PharmAust can move ahead with the upcoming clinical trials in dogs with confidence. Given dogs have an apparently higher taste sensitivity than humans, PharmAust

is also confident this new tablet will be similarly suitable for re-entry into clinical trials in humans.”

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About PharmAust (PAA):

PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company which generated ~Aus\$3.02m in revenues in the 2018 FY.

About BRI

BRI is a Vancouver, Canada, based company that provides specialized and integrated preclinical drug development contract research services for worldwide regulatory submissions for over 20 years. BRI is accredited by Standard Council of Canada for its GLP compliance. BRI boasts a successful track record in providing accurate and quality data in conformance with GLP, GCP and cGMP regulations of the USFDA, OECD and MHLW (Japan).

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs over 11,000 people, including over 1,800 scientists, at more than 30 facilities across five continents, and in fiscal 2018 generated approximately \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

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